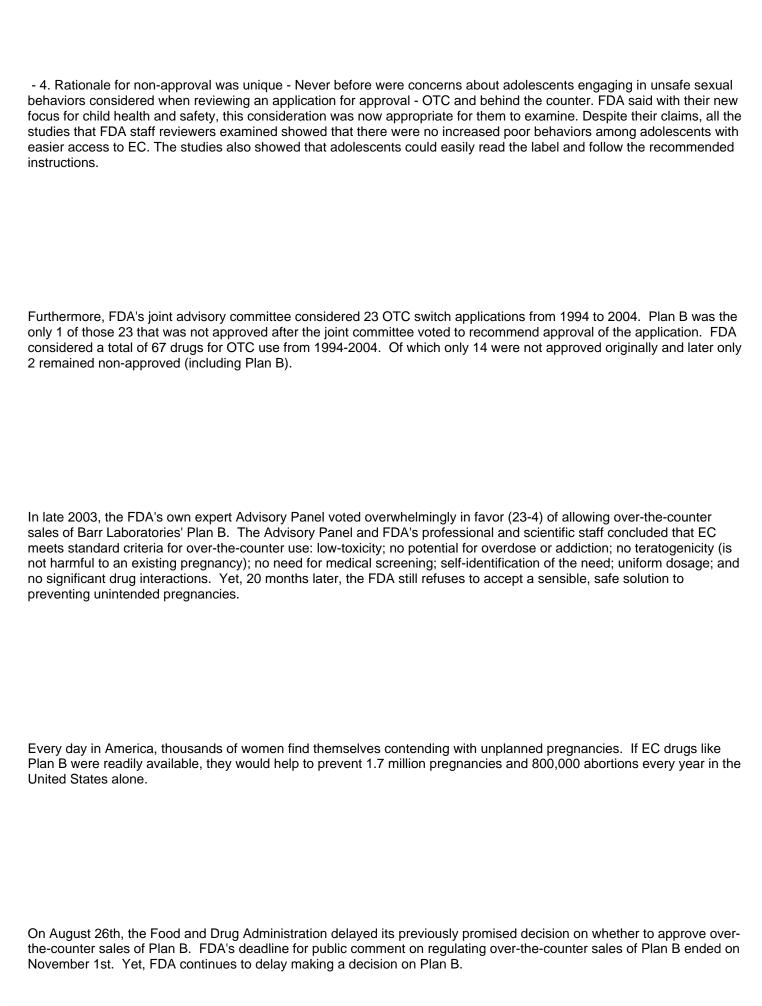
Nov 14 2005 - Slaughter Reacts to GAO Report on FDA's Decision on O.T.C. Sale of

Plan B
Slaughter Reacts to GAO Report on FDA's Decision on O.T.C. Sale of Plan B
Calls Document "Smoking Gun" Proving that Politics Trumped Science at Agency
Washington, DC - Rep. Louise M. Slaughter (D-Fairport), Ranking Member of the House Rules Committee, today released the following statement in response to the public release of a GAO report documenting the reasons behind the FDA's recent refusal to approve the over-the-counter sale of Plan B emergency contraception.
"This report is the 'smoking gun' which clearly demonstrates that the FDA based its decision on politics, and not science. A once trusted and highly respected agency, which based its decisions on the principles of science, has now been taken over by an extremist political agenda.
We commend GAO for conducting this difficult investigation with the utmost professionalism and integrity, and for shedding light on what can only be described as the intentional corruption of the established FDA approval process in th interests of a political agenda.
With this new information, we urge senior FDA officials to stop playing politics with the health and welfare of this country and immediately approve over-the-counter sales of Plan B.

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I am also calling on my colleagues in Congress to hold hearings on this abuse of power and authority by the FDA to promote a blatantly political agenda."
BACKGROUND
GAO found that there were 4 unusual aspects to FDA's decision in May 2004 to not approve Barr Laboratories' application for over-the-counter sales of Plan B.
- 1. Directors did not sign non-approval letter - Directors of the Offices of Drug Evaluations III and V and the Director of the Office of New Drugs did not agree with the decision and did not sign the not-approvable letter.
- 2. Higher level than usual involvement in the decision - the review process for the Plan B OTC switch application was
marked by FDA high-level management that was not typical for OTC switch applications. The acting Director of CDER (Center for Drug Evaluation and Research) signed non-approval letter. This is unusual. The Director has never signed an
OTC letter before and he only signed a couple approval letters for prescription use of drugs.
- 3. Timeframe for decision is murky - FDA staff charged with reviewing the application claimed the decision for non-approval was announced at a reviewer staff meeting in January 2004, well before the review was finished. The original
date for FDA to make a decision was set for Feb. 22 but then it was moved to May 2004, when Barr Labs agreed to provide more information on studies in adolescents.

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